EXHIBIT T

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SILVERGATE PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ANNORA PHARMA PRIVATE LIMITED,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Silvergate Pharmaceuticals, Inc. ("Silvergate" or "Plaintiff"), by and through its attorneys, brings this Complaint for Patent Infringement against Defendant Annora Pharma Private Limited ("Annora" or "Defendant"), and alleges as follows:

THE NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent Nos. 10,772,868 ("the '868 Patent"), 10,786,482 ("the '482 Patent"), and 10,799,476 ("the '476 Patent") (collectively, the "Patents-in-Suit") under the patent laws of the United States, Title 35, United States Code, arising out of the submission by Annora of Abbreviated New Drug Application ("ANDA") No. 214467 to the U.S. Food and Drug Administration ("FDA") seeking approval of a generic version of Silvergate's oral solution formulation that is the subject of New Drug Application ("NDA") No. 208686, hereinafter referred to as Silvergate's "Epaned® Product." Silvergate seeks all available relief under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and other applicable laws for Annora's infringement of the Patents-in-Suit.

2. This is also an action under 35 U.S.C. §§ 2201-02 for a declaratory judgment of infringement of the '476 patent under 35 U.S.C. §§ 271(a), (b), and (c).

THE PARTIES

3. Silvergate is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 8 Cabot Road, Suite 2000, Woburn, MA 01801.

4. Silvergate is a wholly-owned subsidiary of Azurity Pharmaceuticals, Inc. ("Azurity").

5. On information and belief, Annora is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at Sy. No. 261, Annaram Village, Gummadidala Mandal, Sangareddy Dist., Telangana State, 502313, India.

6. On information and belief, Annora is in the business of, among other things, developing, manufacturing, marketing, importing, and selling generic copies of branded pharmaceutical products for the United States market.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America, 35 U.S.C. § 100, *et seq*., and from Annora's submission of ANDA No. 214467.

8. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a). Relief is sought under 35 U.S.C. § 271(e)(2).

9. On information and belief, this Court has personal jurisdiction over Annora because of, among other things, Annora's persistent and continuous contacts with Delaware. Annora has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Annora regularly and continuously transacts business in Delaware, including by directly or indirectly developing, manufacturing, marketing, and selling generic pharmaceutical products in Delaware. On information and belief, Annora derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware. Annora

has regularly engaged in patent litigation concerning FDA-approved products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court, including in a case involving the same ANDA (*Silvergate Pharmaceuticals, Inc. v. Annora Pharma Private Limited*, C.A. No. 20-753-LPS, D.I. 8 (D. Del. Oct. 19, 2020)). *See also*, *e.g.*, *Boehringer Ingelheim Pharms. Inc. v. Annora Pharma Private Ltd.*, C.A. No. 20-277-CFC, D.I. 8 (D. Del. Apr. 27, 2020); *Amgen Inc. v. Annora Pharma Private Ltd.*, C.A. No. 20-122-CFC, D.I. 9 (D. Del. Mar. 26, 2020); *Vifor Fresenius Med. Care Renal Pharma Ltd. v. Annora Pharma Private Ltd.*, C.A. No. 18-1996-MN, D.I. 12 (D. Del. Mar. 1, 2019); *Boehringer Ingelheim Pharms. Inc. v. Annora Pharma Private Ltd.*, C.A. No. 18-1786-CFC-SRF, D.I. 19 (D. Del. Jan. 18, 2019).

10. Additionally, on information and belief, this judicial district is a likely destination of the product that is the subject of ANDA No. 214467.

11. Alternatively, this Court has personal jurisdiction over Annora pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Silvergate's claims arise under federal law; (b) Annora is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Annora has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDA No. 214467 to FDA and/or manufacturing, importing, offering to sell, and/or selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Annora satisfies due process.

12. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c). Annora is a foreign corporation not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(c).

SILVERGATE'S EPANED® PRODUCT

13. Silvergate's Epaned® product is the only FDA approved and labeled ace inhibitor treatment that is a ready-to-use oral solution for hypertension in children. Epaned® is also indicated to treat hypertension in adults, heart failure, and asymptomatic left ventricular dysfunction.

14. Azurity is the holder of approved NDA No. 208686.

PATENTS-IN-SUIT

15. The '868 Patent, entitled "Enalapril Formulations," issued to Gerold Mosher and David Miles on September 15, 2020 from United States Patent Application 16/242,898 (the "'898 Application"). A true and correct copy of the '868 Patent is attached to this Complaint as Exhibit A.

16. The '868 Patent was duly and legally issued to Silvergate as the assignee. Silvergate owns all rights, titles, and interests in the '868 Patent.

17. Pursuant to 21 U.S.C. § 355, the '868 Patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 208686 (Silvergate's Epaned® Product).

18. The '482 Patent, entitled "Enalapril Formulations," issued to Gerold Mosher and David Miles on September 29, 2020 from United States Patent Application 16/17,159 (the "'159 Application"). A true and correct copy of the '482 Patent is attached to this Complaint as Exhibit B.

19. The '482 Patent was duly and legally issued to Silvergate as the assignee, and Silvergate owns all rights, title, and interest in the '482 Patent.

20. Pursuant to 21 U.S.C. § 355, the '482 Patent is listed in the Orange Book in connection with NDA No. 208686 (Silvergate's Epaned® Product).

21. Silvergate's Epaned® Product is covered by at least one claim of each of the '868 and '482 Patents.

22. The '476 Patent, entitled "Enalapril Formulations," issued to Gerold Mosher and David Miles on October 13, 2020 from United States Patent Application 16/883,553 (the "'553 Application"). A true and correct copy of the '476 Patent is attached to this Complaint as Exhibit C.

23. The '476 Patent was duly and legally issued to Silvergate as the assignee, and Silvergate owns all rights, title, and interest in the '476 Patent.

INFRINGEMENT BY ANNORA

24. By letter dated December 23, 2020 ("Notice Letter") Annora notified Silvergate that Annora had submitted ANDA No. 214467 to the FDA pursuant to Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95) to obtain approval to engage in the commercial manufacture, use, and sale of a generic version of Silvergate's Epaned® product (the Annora ANDA Product) before the expiration of the Patents-in-Suit.

25. Each of the '868, '482, and '476 patents expire on March 25, 2036.

26. On information and belief, Annora intends to engage in the commercial manufacture, use, and sale of the Annora ANDA Product promptly upon receiving FDA approval to do so.

27. On information and belief, Annora is seeking approval to engage in the commercial manufacture, use, and sale of the Annora ANDA Product before the expiration of the Patents-in-Suit.

28. By submitting ANDA No. 214467, Annora has necessarily represented to FDA that the Annora ANDA Product has the same active ingredients as Silvergate's Epaned® Product; has

the same route of administration, dosage form, use, and strength as Silvergate's Epaned® Product; and is bioequivalent to Silvergate's Epaned® Product.

CLAIMS FOR RELIEF

Count I—Infringement of the '868 Patent

29. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

30. Annora submitted or caused the submission of ANDA No. 214467 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Annora ANDA Product throughout the United States before the expiration of the '868 Patent. By submitting ANDA No. 214467, Annora has committed an act of infringement of one or more claims of the '868 Patent under 35 U.S.C. § 271(e)(2)(A).

31. If Annora's ANDA No. 214467 is approved by FDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Annora ANDA Product will constitute acts of infringement, either literally or under the doctrine of equivalents, of the '868 Patent under 35 U.S.C. § 271(a) unless enjoined by the Court.

32. If Annora's ANDA No. 214467 is approved by FDA, Annora will induce infringement of one of more claims of the '868 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Annora's ANDA Products in the United States. On information and belief, upon FDA approval of Annora's ANDA Products, Annora will intentionally encourage acts of direct infringement with knowledge of the '868 patent and knowledge that its acts are encouraging infringement unless enjoined by the Court.

33. If Annora's ANDA No. 214467 is approved by FDA, Annora will contributorily infringe one of more claims of the '868 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Annora's ANDA Products in the United Sates, unless enjoined by this Court. On information and belief, Annora has had, and continues to have, knowledge that

Annora's ANDA Products are especially adapted for a use that infringes one or more claims of the '868 patent and that there is no substantial non-infringing use for Annora's ANDA Products.

34. On information and belief, Annora has actual and constructive knowledge of the '868 Patent and is aware that submission of ANDA No. 214467 to FDA constituted an act of infringement of the '868 Patent. In addition, on information and belief, Annora has specific intent to infringe the '868 Patent. Moreover, there are no substantial non-infringing uses for the Annora ANDA Product other than as the pharmaceutical claimed in the '868 Patent.

35. The commercial manufacture, use, offer for sale, sale, and/or importation of the Annora ANDA Product in violation of Silvergate's patent rights will cause substantial and irreparable harm to Silvergate for which damages are inadequate.

Count II—Infringement of the '482 Patent

36. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

37. Annora submitted or caused the submission of ANDA No. 214467 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Annora ANDA Product throughout the United States before the expiration of the '482 Patent. By submitting ANDA No. 214467, Annora has committed an act of infringement of one or more claims of the '482 Patent under 35 U.S.C. § 271(e)(2)(A).

38. If Annora's ANDA No. 214467 is approved by the FDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Annora ANDA Product will constitute acts of infringement, either literally or under the doctrine of equivalents, of the '482 Patent under 35 U.S.C. § 271(a) unless enjoined by the Court.

39. On information and belief, if Annora's ANDA No. 214467 is approved by the FDA, Annora will induce infringement of one of more claims of the '482 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Annora's ANDA Products in the United States. On information and belief, upon FDA approval of Annora's ANDA Products, Annora will intentionally encourage acts of direct infringement with knowledge of the '482 patent and knowledge that its acts are encouraging infringement unless enjoined by the Court.

40. On information and belief, if Annora's ANDA No. 214467 is approved by the FDA, Annora will contributorily infringe one of more claims of the '482 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Annora's ANDA Products in the United Sates, unless enjoined by this Court. On information and belief, Annora has had, and continues to have, knowledge that Annora's ANDA Products are especially adapted for a use that infringes one or more claims of the '482 patent and that there is no substantial non-infringing use for Annora's ANDA Products.

41. On information and belief, Annora has actual and constructive knowledge of the '482 Patent and is aware that submission of ANDA No. 214467 to FDA constituted an act of infringement of the '482 Patent. In addition, on information and belief, Annora has specific intent to infringe the '482 Patent. Moreover, there are no substantial non-infringing uses for the Annora ANDA Product other than as the pharmaceutical claimed in the '482 Patent.

42. The commercial manufacture, use, offer for sale, sale, and/or importation of the Annora ANDA Product in violation of Silvergate's patent rights will cause substantial and irreparable harm to Silvergate for which damages are inadequate.

Count III—Infringement of the '476 Patent

43. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

44. Annora submitted or caused the submission of ANDA No. 214467 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Annora ANDA Product throughout the United States before the expiration of the '476 Patent. By submitting ANDA No. 214467, Annora has committed an act of infringement of one or more claims of the '476 Patent under 35 U.S.C. § 271(e)(2)(A).

45. There is an immediate and justiciable controversy between Silvergate and Annora as to the infringement of the '476 patent.

46. If Annora's ANDA No. 214467 is approved by FDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Annora ANDA Product will constitute acts of infringement, either literally or under the doctrine of equivalents, of the '476 Patent under 35 U.S.C. § 271(a) unless enjoined by the Court.

47. On information and belief, if Annora's ANDA No. 214467 is approved by FDA, Annora will induce infringement of one of more claims of the '476 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Annora's ANDA Products in the United States. On information and belief, upon FDA approval of Annora's ANDA Products, Annora will intentionally encourage acts of direct infringement with knowledge of the '476 patent and knowledge that its acts are encouraging infringement unless enjoined by the Court.

48. On information and belief, if Annora's ANDA No. 214467 is approved by the FDA, Annora will contributorily infringe one of more claims of the '476 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Annora's ANDA Products in the United Sates, unless enjoined by this Court. On information and belief, Annora has had, and continues to have, knowledge that Annora's ANDA Products are especially adapted for a use that

infringes one or more claims of the ’476 patent and that there is no substantial non-infringing use for Annora’s ANDA Products

49. On information and belief, Annora has actual and constructive knowledge of the ’476 Patent and is aware that submission of ANDA No. 214467 to FDA constituted an act of infringement of the ’476 Patent. In addition, on information and belief, Annora has specific intent to infringe the ’476 Patent. Moreover, there are no substantial non-infringing uses for the Annora ANDA Product other than as the pharmaceutical claimed in the ’476 Patent.

50. Silvergate will be substantially and irreparably damaged and harmed if Annora’s infringement of the ’476 patent is not enjoined.

51. Silvergate does not have an adequate remedy at law.

52. The commercial manufacture, use, offer for sale, sale, and/or importation of the Annora ANDA Product in violation of Silvergate’s patent rights will cause substantial and irreparable harm to Silvergate for which damages are inadequate.

Count IV—Declaratory Judgment of Infringement of the ’476 Patent Under 35 U.S.C. §271(a)-(c)

53. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

54. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

55. There is an actual case or controversy such that the Court may entertain Silvergate’s request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

56. On information and belief, Annora will engage in and/or induce another to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Annora’s ANDA No. 214467 immediately and imminently upon approval of ANDA No. 214467.

57. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Annora's ANDA No. 214467 will constitute an act of direct infringement of one or more claims of the '476 Patent.

58. On information and belief, if Annora's ANDA No. 214467 is approved by FDA, Annora will induce infringement of one of more claims of the '476 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Annora's ANDA Products in the United States. On information and belief, upon FDA approval of Annora's ANDA Products, Annora will intentionally encourage acts of direct infringement with knowledge of the '476 patent and knowledge that its acts are encouraging infringement unless enjoined by the Court.

59. On information and belief, if Annora's ANDA No. 214467 is approved by the FDA, Annora will contributorily infringe one of more claims of the '476 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Annora's ANDA Products in the United Sates, unless enjoined by this Court. On information and belief, Annora has had, and continues to have, knowledge that Annora's ANDA Products are especially adapted for a use that infringes one or more claims of the '476 patent and that there is no substantial non-infringing use for Annora's ANDA Products.

60. The foregoing actions by Annora will constitute infringement of the '476 patent.

61. Annora will commit those acts of infringement without license or authorization.

62. Silvergate is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Annora's ANDA No. 214467 by Annora will infringe the '476 Patent.

63. Silvergate does not have an adequate remedy at law.

64. The commercial manufacture, use, offer for sale, sale, and/or importation of the Annora ANDA Product in violation of Silvergate's patent rights will cause substantial and irreparable harm to Silvergate for which damages are inadequate.

PRAYER FOR RELIEF

Silvergate respectfully requests the following relief:

a) A judgment that Annora has infringed the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 214467 under Section 505(j) of the FDCA, and that Annora's making, using, offering to sell, or selling in the United States or importing into the United States of the Annora ANDA Product will infringe, either literally or under the doctrine of equivalents, one or more claims of the Patents-in-Suit;

b) That a declaration be issued under 28 U.S.C. § 2201 that if Annora, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf engage in the commercial manufacture, use, offer for sale, sale and/or importation of the product that is the subject of Annora's ANDA No. 214467, it will constitute an act of infringement of the '476 patent under 35 U.S.C. § 271(a), (b), and (c);

c) A finding that the Patents-in-Suit are valid and enforceable;

d) An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 214467 shall be a date which is not earlier than the latest expiration date of the Patents-in-Suit, as extended by any applicable periods of exclusivity;

e) An order under 35 U.S.C. § 27l(e)(4)(B) permanently enjoining Annora, its subsidiaries, parents, officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, sale, or importation into the United States, of any drug product the use of which is covered by the Patents-in-Suit, including the Annora ANDA Product;

f) A finding that this is an exceptional case under 35 U.S.C. § 285, and that Silvergate be awarded reasonable attorneys' fees and costs; and

g) An award of any such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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